

congressional review requirements in 5 U.S.C. 801–808.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Parts 520 and 522

Animal drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510, 520, and 522 are amended as follows:

PART 510—NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

§ 510.600 [Amended]

■ 2. In § 510.600, in the table in paragraph (c)(1), remove the entries for “Church & Dwight Co., Inc.” and “Peptech Animal Health Pty, Ltd.”; and in the table in paragraph (c)(2), remove the entries for “010237” and “064288”.

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 3. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 520.580 [Amended].

■ 4. In paragraph (b)(1) of § 520.580, remove “010237.”

§ 520.2043 [Amended]

■ 5. In paragraph (b)(2) of § 520.2043, remove “010237” and in its place add “055246”.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 6. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 7. In § 522.533, revise the section heading and paragraph (b), add paragraph (c), and remove paragraph (d) to read as follows:

§ 522.533 Deslorelin.

* * * * *

(b) *Sponsor.* See No. 043264 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses and ponies—*(1) *Amount.* One implant per mare subcutaneously in the neck.

(2) *Indications for use.* For inducing ovulation within 48 hours in estrous mares with an ovarian follicle greater than 30 millimeters in diameter.

(3) *Limitations.* Do not use in horses or ponies intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: August 23, 2010.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2010–21296 Filed 8–26–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF STATE

22 CFR Parts 124, 125, 126, and 129

[Public Notice: 7134]

RIN 1400–AC62

Amendment to the International Traffic in Arms Regulations: Removing Requirement for Prior Approval for Certain Proposals to Foreign Persons Relating to Significant Military Equipment

AGENCY: Department of State.

ACTION: Final rule.

SUMMARY: The Department of State is amending the International Traffic in Arms Regulations (ITAR) to remove the requirements for prior approval or prior notification for certain proposals to foreign persons relating to significant military equipment.

DATES: *Effective Date:* This rule is effective August 27, 2010.

FOR FURTHER INFORMATION CONTACT: Director Charles Shotwell, Office of Defense Trade Controls Policy, Department of State, Telephone (202) 663–2792 or Fax (202) 261–8199; E-mail DDTCResponseTeam@state.gov. ATTN: Regulatory Change, Section 126.8.

SUPPLEMENTARY INFORMATION: In accordance with the President’s Export Control Reform effort, on March 29, 2010, the Department published a Notice of Proposed Rulemaking (NPRM) to eliminate the requirements for prior approval or prior notification for certain proposals to foreign persons relating to significant military equipment at § 126.8 of the ITAR. Effective September 1, 1977, the Department of State amended § 123.16 to require Department of State approval before a proposal or presentation is made that is designed to constitute the basis for a decision to purchase significant combat equipment,

involving the export of an item on the U.S. Munitions List, valued at \$7,000,000 or more for use by the armed forces of a foreign country (42 FR 41631, dated August 18, 1977). Also, § 124.06, entitled, “Approval of proposals for technical assistance and manufacturing license agreements,” was amended to require similar prior approval with respect to proposals and presentations for technical assistance and manufacturing license agreements involving the production or assembly of significant combat equipment.

“Proposals to foreign persons relating to significant military equipment” became § 126.8 in a final rule effective January 1, 1985 (49 FR 47682, dated December 6, 1984). Section 126.8 did not require prior approval of the Department of State when the proposed sale was to the armed forces of a member of the North Atlantic Treaty Organization (NATO), Australia, Japan, or New Zealand, except with respect to manufacturing license agreements or technical assistance agreements.

A prior notification requirement, instead of prior approval, was added to § 126.8 in a final rule effective March 31, 1985 (50 FR 12787, dated April 1, 1985). Prior notification to the Department of State was required 30 days in advance of a proposal or presentation to any foreign person where such proposals or presentations concerned equipment previously approved for export.

The current § 126.8 requires prior approval or prior notification for certain proposals and presentations to make a determination whether to purchase significant military equipment valued at \$14,000,000 or more (other than a member of NATO, Australia, New Zealand, Japan, or South Korea), or whether to enter into a manufacturing license agreement or technical assistance agreement for the production or assembly of significant military equipment, regardless of dollar value.

These types of proposals and presentations usually involve large dollar amounts. Before the defense industry undertakes the effort involved in formulating its proposals and presentations, if there is any doubt that the corresponding license application or proposed agreement would be authorized by the Department of State, the industry may request an advisory opinion (*see* § 126.9). The written advisory opinion, though not binding on the Department, helps inform the defense industry whether the Department would likely grant a license application or proposed agreement. Currently, the time between submitting a license application or proposed

agreement and obtaining a decision from the Department of State whether to authorize such transactions has been decreased sufficiently that requiring prior approval or prior notification for proposals is unnecessary and imposes an administrative burden on industry.

References to § 126.8 have been removed at §§ 124.1(a), 125.4(a), 126.13, 129.7(e), and 129.8(c).

The Proposed Rule had a comment period ending May 28, 2010. Three parties filed comments by May 28 recommending changes. Having thoroughly reviewed and evaluated the comments and the recommended changes, the Department has determined that it will, and hereby does, adopt the Proposed Rule, with minor edits, and promulgates it as a Final Rule. The Department's evaluation of the written comments and recommendations follows.

Comment Analysis

One commenting party commended the proposed change as removing an unnecessary and redundant licensing burden, without suggesting any changes.

One commenting party supported the proposed change, but recommended certain "clerical" changes to other parts of the ITAR for purposes of consistency. Specifically, § 126.1(e) requires the Directorate of Defense Trade Controls' (DDTC) written approval or a license prior to a proposal to sell defense articles or services to any country covered in that section (*i.e.*, restricted destinations). The commenting party suggested the definition of "proposal" in § 126.8(b) be incorporated into § 126.1(e). We believe the incorporation of the § 126.8(b) definition of "proposal" could confuse exporters, potentially encouraging "preliminary discussions" with prohibited destinations. Therefore, we do not support that change. We do, however, concur with this commenting party's recommendation that we delete the references to § 126.8 in §§ 124.1(a), 125.4(a), and 129.7(e). This has been accomplished in our proposed change to § 124.1(a). Appropriate changes to § 125.4(a) and § 129.7(e) have been added to this notice.

One commenting party expressed concern that the elimination of the prior notification requirement would contravene "the fundamental goals of the ITAR" through arms deals furthering the persecution of individuals, denial of human rights, terrorism, and genocide, with special concern about foreign military sales. We note at the outset that foreign military sales are not controlled by the ITAR, as opposed to direct commercial sales. We also note that we are not lessening control over the export

of any defense article, technology, or service. Nor are we lessening scrutiny over prohibited/restricted destinations (§ 126.1(e) remains in place). Rather, we are eliminating the requirement for reviewing an export transaction twice, which we consider to be a redundant burden on industry and government.

One commenting party stated that the change would "limit or eliminate the President's ability to remain informed of 'negotiations' * * *" in contravention of the spirit of § 2778(a)(3) of the Arms Export Control Act (AECA). Our experience from a practical day-to-day review of exports gives us a different perspective. We note that advance notice of pending export transactions was a meaningful concept in the days when the average license processing time was over 60 days. But when the average processing time is approximately 15 days, it is easier and faster to review the export transaction (*e.g.*, manufacturing licensing agreement) as a whole rather than piecemeal. With the challenge of over 84,000 licenses per year, a requirement to review export transactions (in effect) twice is an unnecessary burden that provides the executive branch with effectively no advance notice. Most importantly, the requirement to obtain a license or other authorization before passing ITAR controlled technical data remains in place, placing a significant limitation on the content of negotiations. Furthermore, we will maintain the § 126.1(e) requirement of notice for proposed transactions with restricted destinations, where in most cases there would be a presumption against the export.

The same commenting party also advised that an unintended consequence of the change is the "elimination of any recordkeeping requirements" for proposals. We do not agree, since the § 126.8 requirement to report certain proposals is an obligation separate and independent from recordkeeping requirements. It will continue to be good practice to maintain records of such transactions for an appropriate duration in compliance with § 122.5, particularly to rebut any post hoc allegations that ITAR controlled technical data were transferred without a license or authorization.

The same commenting party recommended alternatively that § 126.8 be retained, but the definition of "proposal" in § 126.8(b) be expanded to better define what constitutes "sufficient detail." For the reasons already mentioned above, we believe that elimination of § 126.8 altogether is simpler and less confusing than

whittling away at the definition of proposal. Another alternative recommended was elimination of § 126.8, but replacement with an exemption. We note that exemptions are used to exempt transactions from licensing requirements when they would otherwise apply. If we eliminate § 126.8, there would be no requirement from which the exporter would require exemption. Therefore, the recommendation is rejected.

Finally, we disagree with the commenting party's allegation that by this action DDTC would "abandon its authority to implement § 2778(a)(3) of the AECA." Since the operative language was that the "President *may* require that persons engaged in the negotiation of defense articles and services keep the President fully and currently informed of the progress and future prospects of such negotiations," this is a discretionary authority. Practical experience has demonstrated that the prior notification/approval requirement is an unnecessary burden on industry without adding any information of value to DDTC's review of exports.

Regulatory Analysis and Notices

Administrative Procedure Act

This amendment involves a foreign affairs function of the United States and, therefore, is not subject to the procedures contained in 5 U.S.C. 553 and 554.

Regulatory Flexibility Act

Since this amendment is not subject to 5 U.S.C. 553, it does not require analysis under the Regulatory Flexibility Act.

Unfunded Mandates Reform Act of 1995

This amendment does not involve a mandate that will result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more in any year and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996

This amendment has been found not to be a major rule within the meaning of the Small Business Regulatory Enforcement Fairness Act of 1996.

Executive Orders 12372 and 13132

This amendment will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the

distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132, it is determined that this amendment does not have sufficient federalism implications to require consultations or warrant the preparation of a federalism summary impact statement. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities do not apply to this amendment.

Executive Order 12866

This amendment is exempt from review under Executive Order 12866, but has been reviewed internally by the Department of State to ensure consistency with the purposes thereof.

Executive Order 12988

The Department of State has reviewed the proposed amendments in light of sections 3(a) and 3(b)(2) of Executive Order 12988 to eliminate ambiguity, minimize litigation, establish clear legal standards, and reduce burden.

Executive Order 13175

The Department of State has determined that this rulemaking will not have tribal implications, will not impose substantial direct compliance costs on Indian tribal governments, and will not pre-empt tribal law. Accordingly, the requirement of Section 5 of Executive Order 13175 does not apply to this rulemaking.

Paperwork Reduction Act

This rule does not impose any new reporting or recordkeeping requirements subject to the Paperwork Reduction Act, 44 U.S.C. Chapter 35.

List of Subjects

22 CFR Parts 124 and 129

Arms and munitions, Exports, Technical assistance.

22 CFR Part 125

Arms and munitions, Exports.

22 CFR Part 126

Arms and munitions, Exports.

■ Accordingly, for the reasons set forth above, Title 22, Chapter I, Subchapter M, parts 124, 125, 126, and 129 are amended as follows:

PART 124—AGREEMENTS, OFF-SHORE PROCUREMENT AND OTHER DEFENSE SERVICES

■ 1. The authority citation for part 124 is revised to read as follows:

Authority: Secs. 2, 38, and 71, Pub. L. 90–629, 90 Stat. 744 (22 U.S.C. 2752, 2778, 2797); E.O. 11958, 42 FR 4311; 3 CFR, 1977 Comp., p. 79; 22 U.S.C. 2651a; 22 U.S.C. 2776; Pub. L. 105–261.

■ 2. Section 124.1 is amended by revising paragraph (a) to read as follows:

§ 124.1 Manufacturing license agreements and technical assistance agreements.

(a) *Approval.* The approval of the Directorate of Defense Trade Controls must be obtained before the defense services described in § 120.9(a) of this subchapter may be furnished. In order to obtain such approval, the U.S. person must submit a proposed agreement to the Directorate of Defense Trade Controls. Such agreements are generally characterized as manufacturing license agreements, technical assistance agreements, distribution agreements, or off-shore procurement agreements, and may not enter into force without the prior written approval of the Directorate of Defense Trade Controls. Once approved, the defense services described in the agreements may generally be provided without further licensing in accordance with §§ 124.3 and 125.4(b)(2) of this subchapter. The requirements of this section apply whether or not technical data is to be disclosed or used in the performance of the defense services described in § 120.9(a) of this subchapter (e.g., all the information relied upon by the U.S. person in performing the defense service is in the public domain or is otherwise exempt from licensing requirements of this subchapter pursuant to § 125.4 of this subchapter). This requirement also applies to the training of any foreign military forces, regular and irregular, in the use of defense articles. Technical assistance agreements must be submitted in such cases. In exceptional cases, the Directorate of Defense Trade Controls, upon written request, will consider approving the provision of defense services described in § 120.9(a) of this subchapter by granting a license under part 125 of this subchapter.

* * * * *

PART 125—LICENSES FOR THE EXPORT OF TECHNICAL DATA AND CLASSIFIED DEFENSE ARTICLES

■ 3. The authority citation for part 125 is revised to read as follows:

Authority: Secs. 2 and 38, Pub. L. 90–629, 90 Stat. 744 (22 U.S.C. 2752, 2778); E.O. 11958, 42 FR 4311; 3 CFR, 1977 Comp. p. 79; 22 U.S.C. 2651a.

■ 4. Section 125.4 is amended by revising paragraph (a) to read as follows:

§ 125.4 Exemptions of general applicability.

(a) The following exemptions apply to exports of technical data for which approval is not needed from the Directorate of Defense Trade Controls. The exemptions, except for paragraph (b)(13) of this section, do not apply to exports to proscribed destinations under § 126.1 of this subchapter or for persons considered generally ineligible under § 120.1(c) of this subchapter. The exemptions are also not applicable for purposes of establishing offshore procurement arrangements or producing defense articles offshore (see § 124.13), except as authorized under § 125.4(c). Transmission of classified information must comply with the requirements of the Department of Defense National Industrial Security Program Operating Manual (unless such requirements are in direct conflict with guidance provided by the Directorate of Defense Trade controls, in which case the latter guidance must be followed) and the exporter must certify to the transmittal authority that the technical data does not exceed the technical limitation of the authorized export.

* * * * *

PART 126—GENERAL POLICIES AND PROVISIONS

■ 5. The authority citation for part 126 continues to read as follows:

Authority: Secs. 2, 38, 40, 42 and 71, Pub. L. 90–629, 90 Stat. 744 (22 U.S.C. 2752, 2778, 2780, 2791 and 2797); E.O. 11958, 42 FR 4311; 3 CFR, 1977 Comp., p. 79; 22 U.S.C. 2651a; 22 U.S.C. 287c; E.O. 12918, 59 FR 28205; 3 CFR, 1994 Comp., p. 899; Sec. 1225, Pub. L. 108–375.

§ 126.8 [Removed and Reserved]

■ 6. Section 126.8 is removed and reserved.

■ 7. Section 126.13 is amended by revising paragraph (a) introductory text to read as follows:

§ 126.13 Required information.

(a) All applications for licenses (DSP–5, DSP–61, DSP–73, and DSP–85), all requests for approval of agreements and amendments thereto under part 124 of this subchapter, and all requests for written authorizations must include a letter signed by a responsible official empowered by the applicant and addressed to the Directorate of Defense Trade Controls, stating whether:

* * * * *

PART 129—REGISTRATION AND LICENSING OF BROKERS

■ 8. The authority citation for part 129 is revised to read as follows:

Authority: Sec. 38, Pub. L. 104–164, 110 Stat. 1437, (22 U.S.C. 2778).

§ 129.7 [Amended]

■ 9. Section 129.7 is amended by removing paragraph (e).

§ 129.8 [Amended]

■ 10. Section 129.8 is amended by removing paragraph (c).

Dated: August 18, 2010.

Ellen O. Tauscher,

Under Secretary, Arms Control and International Security, Department of State.

[FR Doc. 2010–21451 Filed 8–26–10; 8:45 am]

BILLING CODE 4710–25–P

DEPARTMENT OF STATE**22 CFR Part 125**

[Public Notice: 7135]

RIN 1400–AC59

Amendment to the International Traffic in Arms Regulations: Export Exemption for Technical Data

AGENCY: Department of State.

ACTION: Final rule.

SUMMARY: The Department of State is amending the International Traffic in Arms Regulations (ITAR) to clarify an exemption for technical data. The clarification is that the exemption covers technical data, regardless of media or format, sent or taken by a U.S. person who is an employee of a U.S. corporation or a U.S. Government agency to a U.S. person employed by that U.S. corporation or to a U.S. Government agency outside the United States.

DATES: *Effective Date:* This rule is effective August 27, 2010.

FOR FURTHER INFORMATION CONTACT:

Director Charles Shotwell, Office of Defense Trade Controls Policy, Department of State, Telephone (202) 663–2792 or Fax (202) 261–8199; E-mail DDTCResponseTeam@state.gov. ATTN: Regulatory Change, Section 125.4.

SUPPLEMENTARY INFORMATION: On November 24, 2009, the Department published a Notice of Proposed Rulemaking (NPRM) to add language clarifying 22 CFR 125.4(b)(9) to allow technical data, including classified information, and regardless of media or format, sent or taken by a U.S. person who is an employee of a U.S.

corporation or a U.S. Government agency, to a U.S. person employed by that U.S. corporation or to a U.S. Government agency outside the United States under certain specified circumstances reflected in 22 CFR 125.4(b)(9)(i) through (iii) (74 FR 61292). This amendment will add after the word “information” the words “and regardless of media or format.” Also, the words “sent by a U.S. corporation to a U.S. person employed by that corporation overseas or to a U.S. Government agency” has been replaced by “sent or taken by a U.S. person who is an employee of a U.S. corporation or a U.S. Government agency to a U.S. person employed by that corporation or to a U.S. Government agency outside the United States.” Thus, the exemption will explicitly allow hand carrying technical data by a U.S. person employed by a U.S. corporation or a U.S. Government agency to a U.S. person employed by that U.S. corporation or to a U.S. Government agency outside the United States, as long as certain criteria in §§ 125.4(b)(9) and 125.4(b)(9)(i)–(iii) are met. The word “overseas” will be replaced by “outside the United States” at §§ 125.4(b)(9), 125.4(b)(9)(i), 125.4(b)(9)(ii), and 125.4(b)(9)(iii). Also, § 125.4(b)(9)(iii) will be amended to add the words “or taken” after the word “sent.” As stated in 22 CFR 125.4(a), this exemption does not apply to exports to proscribed destinations under 22 CFR 126.1.

The Proposed Rule had a comment period ending January 25, 2010. Nine parties filed comments by January 25 recommending changes. Having thoroughly reviewed and evaluated the comments and the recommended changes, the Department has determined that it will, and hereby does, adopt the Proposed Rule, with minor edits, and promulgates it as a Final Rule. The Department’s evaluation of the written comments and recommendations follows:

Comment Analysis

One commenting party recommended that “sent or taken” be changed to “sent, taken or accessed.” This recommendation was deemed not necessary since it is implied the U.S. person who is an employee of a U.S. corporation or the U.S. person who is an employee of a U.S. Government agency taking the technical data outside of the United States may access the technical data.

One commenting party inquired whether a U.S. corporation (manufacturer) could use the exemption to send (orally or via e-mail) technical

data to an employee of a U.S. Government agency outside the United States, as well as what steps the U.S. manufacturer would take to ensure that 22 CFR 125.4(b)(9)(i)–(ii) are met. The U.S. corporation (in compliance with 22 CFR part 122) is able to use the exemption to send (orally or via e-mail) technical data to a U.S. person employed by a U.S. Government agency outside the United States, so long as the U.S. company takes reasonable precautions to ensure that conditions in 22 CFR 125.4(b)(9)(i) through (ii) are met:

1. The technical data will be used outside of the United States solely by U.S. persons; and

2. The U.S. person outside of the United States is employed by a U.S. Government agency.

Two commenting parties recommended that it be explicit that the technical data could be for “personal use” by the U.S. person claiming the exemption. That recommendation was not adopted since it introduced uncertainty about uses beyond those related to employment.

One commenting party pointed out that when technical data is exported from a U.S. port using an exemption, the ITAR does not require the report of such an export using the Automated Export System (AES); instead, the exporter is to provide electronic notification directly to the Directorate of Defense Trade Controls (DDTC) (*see* 22 CFR 123.22(b)(3)(iii)). The commenting party recommended that if the system to electronically file directly to DDTC is not going to be implemented, then DDTC should arrange for AES to be the reporting mechanism. The commenting party also recommended that if classified technical data is being exported under the provisions of the Department of Defense National Industrial Security Program Operating Manual, an Electronic Export Information should be filed within AES. For exports of technical data using exemptions, there is no system to electronically file directly to DDTC. DDTC is reviewing carefully the possibility of having all exports of technical data using an exemption be reported using an Electronic Export Information within Census Bureau’s Automated Export System.

Two commenting parties recommended the exemption at § 125.4(b)(9) be expanded so the exporter would be a U.S. person who is an employee of any entity, organization, or group incorporated or organized to do business in the United States. Also, the recipient would be a U.S. person employed by that entity, organization,